

**REMARKS**

Claims 18-24, 28-35 and 47 are pending in the application. Claim 28 has been withdrawn from consideration by the Examiner and is now cancelled by Applicant without prejudice. Claims 51 and 53 are also cancelled by Applicant without prejudice. Applicant has amended Claim 52 by changing its dependency from newly canceled claim 51 to claim 19.

***35 U.S.C. §112***

Claim 51 is rejected under 35 U.S.C. §112 1st paragraph as failing to comply with the written description requirement. The Office Action asserts that the phrase "... wherein the coating provides systemic delivery of at least 25% to 50% of the agent upon application of the device to the skin of a subject for 5 seconds..." is new matter that was not in the original specification as filed. The office action asserts that the specification does not support this phrase as applied to all the active agents in the claimed invention.

The Office Action further indicates that only the following limitations of systemic delivery are supported: 26% in 5 seconds for desmopressin, 50% in 5 seconds for hGH and >80% in 5 seconds for albumin.

Applicant respectfully traverses and contends that the support in the specification is not limited to the few exemplifications outlined above by the Office Action. Specifically, the specification discloses that ovalbumin, (which releases 80% in 5 seconds) "is a good model for large pharmaceutical agents such as FSH and erythropoietin" last sentence of paragraph 64 of the published specification. Thus, Applicant contends that the specification supports the claimed breadth of active agents.

However, without acquiescing to the assertion made in the Office Action, and for the purpose only of expediting prosecution of the application, Applicants have herein cancelled claim 51.

Claim 53 is rejected under 35 U.S.C. §112 1st paragraph as failing to comply with the written description requirement.

New claim 53, recites that the coating of claim 19 provides delivery in the skin of at least about 80% of the agent upon application of the device to the skin of a subject for 5 seconds. The office action contends that the specification does not support this statement as applied to all the active agents in the claimed invention.

Applicant respectfully traverses and contends that the support in the specification is not be limited to the few exemplifications designated above by the Office Action. Specifically, the specification discloses that ovalbumin, (which releases 80% in 5 seconds) "is a good model for large pharmaceutical agents such as FSH and erythropoietin", last sentence of paragraph 64 of the published specification. Thus, Applicant contends that the specification supports the claimed breadth of active agents.

However, without acquiescing to the assertion made in the Office Action, and for the purpose only of expediting prosecution of the application, Applicants have herein cancelled claim 53.

#### Provisional Double Patenting Rejections

The Office Action has provisionally rejected claims 18-20, 22-24, 29-35, 47 and 51-53 on grounds of obviousness-type double patenting, as being unpatentable over claims 54-64 of copending application number 11/034,891.

The Office Action has provisionally rejected claims 18-20, 22-24, 29-35, 47 and 51-53 on grounds of obviousness-type double patenting, as being unpatentable over claims 28-54 of copending Application No. 10/127108, over claims 21-39 of copending Application No. 10/674626, over claims 10-13 of copending application No. 10/972231, over claims 33-38 of copending Application No. 11/201625, over claims 32-34 of copending Application No. 11/206698 and over claims 30-35 of copending application No. 11/355,856.

Applicant notes that PAIR shows that 10/674626, 11/201625, 11/206698 and 11/355,856 are each listed as abandoned. Applicant notes that 10/972231 appears to have been abandoned also. Because these applications are not copending with the instant application, Applicant

contends that the provisional rejection of the instant claims on the grounds of obviousness-type double patenting should not stand.

Applicant further traverses the provisional rejection of claims 18-20, 22-24, 29-35, 47 and 51-53 on grounds of obviousness-type double patenting over any of the listed patent applications that are copending with the instant application, including as 10/972231, 11/034,891 and 10/127108, on the grounds that the purported conflicting claims have not in fact been patented. However, in the interest of advancing prosecution, Applicant has attached herewith a terminal disclaimer for each of 10/972231, 11/034,891 and 10/127108.

Applicant has cancelled claims 51 and 53, rendering their provisional rejection moot.

## **CONCLUSION**

In view of the above amendments and remarks, applicant believes the pending application is in condition for allowance. If for any reason the fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105** referencing Docket No. 80929(303655).

Respectfully submitted,

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